

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 27

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GIANNI FRASCOTTI, PAOLA COSMINA
and GUIDO GRANDI

Appeal No. 1996-1042
Application No. 07/810,138

HEARD: March 9, 2000

Before WINTERS, ROBINSON and LORIN, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 9 through 15, which are all of the claims pending in the application.

Appeal No. 1996-1042
Application No. 07/810,138

Claims 9 and 14, which are illustrative of the subject matter on appeal, read as follows:

9. A biologically pure culture of asporogenous strain *Bacillus subtilis* SMS275, suitable for use as a host component in a host-vector system, characterized in that said strain [sic] has a frequency of reversion to spore formers of less than 10^{-8} , plasmid stability, genetic markers leu, pyrD1, apr⁻, npr⁻ and spoII:D [sic], and is deposited as CBS 432.90.

14. A process for the production of a heterologous polypeptide or protein or a precursor thereof, comprising the steps of:

a) transforming an asporogenous strain *Bacillus subtilis* SMS275 with a plasmid vector containing a gene coding for a heterologous polypeptide or protein or a precursor thereof,

wherein said asporogenous strain *Bacillus subtilis* SMS275 is characterized in that it has a frequency of reversion to spore formers of less than 10^{-8} , plasmid stability, genetic markers leu, pyrD1, apr⁻, npr⁻ and spoII:D [sic], and is deposited as CBS 432.90;

b) culturing the transformed asporogenous strain *Bacillus subtilis* of step (a) in a suitable culture medium containing a carbon source, a nitrogen source, mineral salts, leucine and uracil; and

(c) recovering said heterologous polypeptide or protein or a precursor thereof.

The references relied on by the examiner are:

Young et al. (Young)	4,302,544	Nov. 24, 1981
Dean et al. (Dean '235)	4,450,235	May 22, 1984
Dean et al. (Dean '236)	4,450,236	May 22, 1984
Dean et al. (Dean '773)	4,465,773	Aug. 14, 1984
Furutani et al. (Furutani)	5,015,574	May 14, 1991

Appeal No. 1996-1042
Application No. 07/810,138

		(filed Nov. 20, 1986)
Grandi et al. (Grandi)	5,047,333	Sep. 10, 1991
		(filed Dec. 22, 1988)
Mountain	WO 89/04866	Jun. 1, 1989
(PCT patent application)		

Kathleen Sandman et al. (Sandman), "Genetic Analysis of *Bacillus subtilis spo* Mutations Generated by Tn917-Mediated Insertional Mutagenesis," 117 Genetics 603-17 (Dec. 1987)

The issues presented for review are: (1) whether the examiner erred in rejecting claims 9 through 13 under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure; (2) whether the examiner erred in rejecting claim 9 under 35 U.S.C. § 103 as unpatentable over Young, Dean '235, Dean '236, or Dean '773, either of those "primary" references considered in view of Sandman and Mountain; and (3) whether the examiner erred in rejecting claims 10 through 15 under 35 U.S.C. § 103 as unpatentable over Young, Dean '235, Dean '236, or Dean '773, either of those "primary" references considered in view of Sandman, Mountain, and "further in view of" Furutani or Grandi.

On consideration of the record, we reverse the examiner's rejections.

DISCUSSION

Initially, we note that the recitation "spoII:D" in claims 9 and 14 appears to be incorrect. We believe that appellants intend "spoII:D⁻," consistent with the description in the specification, page 5, line 9 and with the recitation of an asporogenous strain of Bacillus subtilis. On return of this application to the Examining Group, we recommend that both appellants and the examiner clarify this matter.

Claims 9 through 13 stand rejected under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure. According to the examiner, the specification does not teach how to make the claimed biologically pure culture of asporogenous strain Bacillus subtilis SMS275, suitable for use as a host component in a host-vector system. We disagree.

As set forth in the specification, page 4, fourth paragraph:

An asporogenous mutant of B.subtilis which overcomes the problems described above has now been isolated. This mutant, known as SMS275, has been deposited on October 5, 1990 at the Centraalbureau Voor Schimmelcultures where it received the number CBS 432.90.

Appeal No. 1996-1042
Application No. 07/810,138

The deposit number CBS 432.90 is also recited in independent claim 9, and the examiner does not contend that appellants fail to comply with the appropriate regulations governing the deposit of biological materials. See 37 CFR § 1.801 et seq. On these facts, we find that appellants' deposit satisfies the statutory requirement for patentability under 35 U.S.C. § 112, first paragraph.

The examiner argues that the claimed biologically pure culture of asporogenous strain Bacillus subtilis SMS275 has a frequency of reversion to spore formers of less than 10^{-8} , and that the specification fails to teach how to make an asporogenous strain of Bacillus subtilis having that characteristic. In our judgment, however, the examiner has not provided adequate reasons explaining why any person skilled in the art would doubt the truth or accuracy of appellants' statement in the specification that their biologically pure culture of asporogenous strain Bacillus subtilis SMS275 has a frequency of reversion to spore formers of less than 10^{-8} . See In re Armbruster, 512 F.2d 676, 677-78, 185 USPQ 152, 153 (CCPA 1975). Accordingly, the examiner has not established a prima facie case of lack of enablement and

Appeal No. 1996-1042
Application No. 07/810,138

we find it unnecessary to discuss the Grandi Declaration, filed under the provisions of 37 CFR § 1.132 and executed February 15, 1994, relied on by appellants as rebutting any such prima facie case.

The rejection of claims 9 through 13 under 35 U.S.C. § 112, first paragraph, is reversed.

Respecting the rejections of claims 9 through 15 under 35 U.S.C. § 103, appellants argue that Young, Dean '235, Dean '236, and Dean '773 disclose asporogenous strains of Bacillus subtilis having a reversion frequency "as low as 10^{-7} " but no lower. See the Appeal Brief, pages 7 and 12. The examiner acknowledges that this is the case, i.e., that the "primary" references teach asporogenous strains of Bacillus subtilis having reversion frequencies "as low as 10^{-7} " but no lower. Nevertheless, the examiner states that "it remains unclear that the strain claimed by appellants has a lower reversion rate than those disclosed in any of the cited references" (Examiner's Answer, page 11, last paragraph).

In resolving questions of obviousness, one must consider the claimed subject matter as a whole. 35 U.S.C. § 103. Here, each independent claim expressly recites the

Appeal No. 1996-1042
Application No. 07/810,138

asporogenous strain Bacillus subtilis SMS275 having a frequency of reversion to spore formers of less than 10^{-8} . It is apparent, therefore, that the claimed strain of Bacillus subtilis has a lower reversion rate (frequency of reversion to spore formers of less than 10^{-8}) than those strains disclosed in the "primary" references (frequency of reversion to spore formers as low as 10^{-7}). Where, as here, the examiner does not adequately consider all of the claim limitations, and does not adequately consider the claimed subject matter as a whole, this constitutes reversible error and we shall not sustain the prior art rejections under 35 U.S.C. § 103.

Appeal No. 1996-1042
Application No. 07/810,138

Furthermore, having carefully reviewed the record, we believe that the examiner has engaged in a hindsight reconstruction of the claimed invention, using the applicants' specification as a template and selecting elements from the references to fill the gaps. This is impermissible. See In re Gorman, 933 F.2d 982, 987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). In our judgment, the examiner relies on hindsight in arguing that a person having ordinary skill would have been led from "here to there," i.e., from the asporogenous strains of Bacillus subtilis disclosed in the prior art to the asporogenous strain Bacillus subtilis SMS275 recited in the appealed claims. The latter strain has a frequency of reversion to spore formers of less than 10^{-8} ; plasmid stability; and five specifically recited genetic markers.

The rejections of claims 9 through 15 under 35 U.S.C. § 103 are reversed.

CONCLUSION

In conclusion, for the reasons set forth in the body of this opinion, we do not sustain the rejection of claims 9 through 13 under 35 U.S.C. § 112, first paragraph, as based on

Appeal No. 1996-1042
Application No. 07/810,138

a non-enabling disclosure. Further, we do not sustain the
rejections

Appeal No. 1996-1042
Application No. 07/810,138

of claims 9 through 15 under 35 U.S.C. § 103 as unpatentable
over the cited prior art.

The examiner's decision rejecting claims 9 through 15 is
reversed.

REVERSED

SHERMAN D. WINTERS)	
Administrative Patent Judge)	
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DOUGLAS W. ROBINSON)	BOARD OF PATENT
Administrative Patent Judge)	APPEALS AND
)	INTERFERENCES
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HUBERT C. LORIN)	
Administrative Patent Judge)	

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Appeal No. 1996-1042
Application No. 07/810,138

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